K010794

MAY 1 0 2001

510(k) Summary
for
Meridian Medical Technologies Ltd
Bridge III Receiver ®

Submitter	Meridian Medical Technologies Ltd 207 Airport Road West, Belfast BT3 9ED Northern Ireland
Contact Name	Rhona Love Manager, QA and Regulatory Affairs
Date of Application	14TH March 2001
Device Name	
Trade Name:	Bridge III Receiver ®
Classification Name:	Telephone electrocardiograph transmitter and receiver per 21 CFR 880.2920

Substantially Equivalent Devices

The BRIDGE III Receiver is substantially equivalent to the LifeSigns ™ Receiving Center 2000 ECG Receiver (K951096).

Description of the Device

The BRIDGE III Receiver is a receiver for the CardioBeeper ® family of heart monitors. It is compatible with both single channel and triple channel CardioBeeper ® transmitters. The receiver is a computer accessory that connects to IBM compatible personal computers (486 and above) via a serial port. The receiver is also directly connected to the telephone line, between the operators handset and the wall socket, to receive the CardioBeeper ® signals. The receiver is designed to act with the Cardiovision ® software.

The Cardiovision ® software controls the receiver facilities and operating modes.

The Bridge III automatically detects an incoming audio signal from a CardioBeeper ® heart monitor. The signal is demodulated to extract the analogue heart trace and then digitised to provide a stream of digital information for plotting by the Cardiovision ® software.

The Bridge III is a 271mm x 145mm x 180mm unit weighing 3.35kg constructed from powder-coated aluminium, which is designed for use in an office environment remote from the location of the ECG trace site.

Intended Use of the Device The Bridge III Receiver is intended to receive an electrocardiographic signal that has been transmitted via telephone from a remote location. Suitable ECG transmitters include the CardioBeeper ® CB12/12 (K002310), CardioBeeper CB250 ® (K983582), CardioBeeper ® CB12L (K965101) and other devices in the CardioBeeper ® range that have received 510(k) approval.

The BRIDGE III receiver interfaces between the telephone line and a personal computer running Cardiovision ® software (K981807).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 0 2001

Ms. Rhona Love
Meridian Medical Technologies Ltd.
207 Airport Road West
Belfast, Co Antrim
Northern Ireland

Re: K010794
Trade/Device Name: Bridge III Receiver
Regulation Number: 870.2920
Regulatory Class: II (two)
Product Code: DXH
Dated: March 14, 2001
Received: March 16, 2001

Dear Ms. Love

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this

response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

Ver/ 3 - 4/24/96

Applicant: MERIDIAN MEDICAL TECHNOLOGIES LTD

510(k) Number (if known):

Device Name: Bridge III Receiver

Indications For Use:

The Bridge III is intended to receive an electrocardiographic signal that has been transmitted via telephone from a remote location. Suitable ECG transmitters include the CardioBeeper ® CB12/12 (K002310), CardioBeeper ® CB250 (K983582), CardioBeeper ® CB12L (K965101) and other devices in the CardioBeeper ® range that have received 510(k) approval.
The Bridge III Receiver interfaces between the telephone line and a personal computer running Cardiovision ® software (K981807).

Division of Cardiovascular & Respiratory Devices
510(k) Number K010794

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)
(Optional Format 1-2-96)